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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,395,767

mailed
JUL 31 2012
OPLA

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,395,767, claims of which cover the human drug product ONGLYZA® (saxaglyptin hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 895 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 895 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 31, 2010 (75 Fed. Reg. 53315), would be 1,510 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	RRP - PGRRP - DD - ½ (TP - PGTP)[1]
	=	2,794 - 172 - 0 - ½ (2,397 - 172)
	=	1,510 days (4.1 years)

Since the regulatory review period began December 8, 2001, before the patent issued (May 28, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 8, 2001, to and including May 28, 2002, is 172 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the

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[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,510 days, would extend the patent from February 16, 2021, to April 6, 2025, which is beyond the 14-year limit (the approval date is July 31,2009, thus, the 14 year limit is July 31, 2023). The period of extension is thus limited to July 31, 2023, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 16, 2021, to and including July 31, 2023, or 895 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,395,767
Granted:	May 28, 2002
Original Expiration Date[2]:	February 16, 2021
Applicant:	Jeffrey A. Robl et al.
Owner of Record:	Bristol-Myers Squibb Company
Title:	Cyclopropyl-fused Pyrrolidine-based Inhibitors of Dipeptidyl Peptidase IV and Method
Product Trade Name:	ONGLYZA® (saxaglyptin hydrochloride)
Term Extended:	895 days
Expiration Date of Extension:	July 31, 2023

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: ONGLYZA® (saxaglyptin hydrochloride)
Docket No.: FDA-2010-E-0061